Notice of Allowability	Application No.	Applicant(s)	
	08/836,455	CHATTERJEE ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *12 November 2004*.

2. ☒ The allowed claim(s) is/are *6,11,16-19,38,59,62,63,65,69-81 and 89-98*.

3. ☒ The drawings filed on *26 September 2002 and 09 May 1997* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20050209* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

LARRY R. HELMS, PH.D
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jill A. Jacobson, Ph.D. on February 8, 2005.

The application has been amended as follows:

In the specification

The following rewritten paragraph replaced the first paragraph of the specification at page 1 beginning in line 6.

This application is a §371 of Application No. PCT/US96/20757, filed December 19, 1996, which claims priority to U.S. Serial No. 08/766,350, filed December 13, 1996, which claims the benefit of provisional application Serial Nos. 60/035,345, converted from U.S. Serial No. 08/591,965, filed January 29, 1996, and ~~also claims the benefit of provisional application Serial No.~~ 60/031,306, converted from U.S. Serial No. 08/575,762, filed December 20, 1995, ~~all~~ each of which provisional applications are incorporated by reference in their entirety.

In the claims

The following listing of claims replaced all prior versions and listings of claims in the application.

Claims 1-5 (canceled)

Claim 6 (previously presented): An isolated polynucleotide comprising a sequence encoding a polypeptide that upon administration to a mammal is capable of eliciting an anti-HMFG immunological response in said mammal, wherein the polypeptide comprises an

immunoglobulin variable region containing the three light chain complementarity determining regions (CDRs) of antibody 11D10 and an immunoglobulin variable region containing the three heavy chain CDRs of antibody 11D10, wherein antibody 11D10 is produced by the hybridoma deposited under ATCC Accession No. HB-12020.

Claims 7-10 (canceled)

Claim 11 (previously presented): A polynucleotide according to claim 6, wherein the encoding sequences for the variable region containing the three light chain CDRs and the encoding sequence for the variable region containing the three heavy chain CDRs are contained in the variable region encoding sequence in SEQ ID NO:1 and SEQ ID NO:3, respectively.

Claims 12-15 (canceled)

Claim 16 (previously presented): A cloning vector comprising the polynucleotide according to claim 6.

Claim 17 (previously presented): An expression vector comprising the polynucleotide according to claim 6.

Claim 18 (original): The expression vector of claim 17, wherein the expression vector is vaccinia.

Claim 19 (previously presented): An isolated host cell comprising the polynucleotide of claim 6.

Claims 20-37 (canceled)

Claim 38 (original): A composition comprising the polynucleotide of claim 6 and a pharmaceutically acceptable excipient.

Claims 39-58 (canceled)

Claim 59 (previously presented): The polynucleotide of claim 6, wherein the polypeptide has the light and heavy chain variable region sequences contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claims 60-61 (canceled)

Claim 62 (previously presented): A polynucleotide according to claim 6, wherein the anti-HMFG immunological response comprises production of anti-HMFG antibody by the mammal.

Claim 63 (previously presented): A polynucleotide according to claim 6, wherein the anti-HMFG immunological response comprises production of anti-HMFG reactive T cells by the mammal.

Claim 64 (canceled)

Claim 65 (previously presented): A polynucleotide according to claim 6, wherein the variable regions are joined by a linker polypeptide of about 5 to 20 amino acids.

Claim 66-68 (canceled)

Claim 69 (previously presented): A method of preparing a heavy chain variable region of antibody 11D10, wherein antibody 11D10 is produced by the hybridoma deposited under ATCC Accession No. HB-12020, comprising expressing the polynucleotide of claim 73 in an isolated host cell.

Claim 70 (previously presented): A kit for eliciting an anti-HMFG immunological response in a mammal comprising the polynucleotide of claim 6 in packaging.

Claim 71 (previously presented): A polynucleotide according to claim 6, wherein the light chain CDRs and the heavy chain CDRs are contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim 72 (previously presented): An isolated polynucleotide encoding an immunoglobulin variable region containing the three light chain CDRs in SEQ ID NO:2.

Claim 73 (previously presented): An isolated polynucleotide encoding an immunoglobulin variable region containing the three heavy chain CDRs in SEQ ID NO:4.

Claim 74 (previously presented): A polynucleotide according to claim 72, wherein the variable region is contained in SEQ ID NO:2.

Claim 75 (previously presented): A polynucleotide according to claim 73, wherein the variable region is contained in SEQ ID NO:4.

Claim 76 (previously presented): A composition comprising the polynucleotide of any of claims 65, 72, 73, 74, or 75 and a pharmaceutically acceptable excipient.

Claim 77 (previously presented): An isolated host cell comprising the polynucleotide of any of claims 59, 71, 72, 73, 74, or 75, wherein the polynucleotide is a recombinant polynucleotide.

Claim 78 (currently amended): A polynucleotide according to any of claims ~~7~~, 11, 59, 62-63, 65, or 71-75, wherein the polynucleotide is a recombinant polynucleotide.

Claim 79 (previously presented): A composition according to claim 38, wherein the polynucleotide is a recombinant polynucleotide.

Claim 80 (currently amended): A kit according to ~~any of claims 57, 58, or~~ claim 70, wherein the polynucleotide is a recombinant polynucleotide.

Claim 81 (previously presented): A composition according to claim 76, wherein the polynucleotide is a recombinant polynucleotide.

Claims 82-88 (canceled)

Claim 89 (previously presented): A method of preparing a light chain variable region of antibody 11D10, wherein antibody 11D10 is produced by the hybridoma deposited under ATCC Accession No. HB-12020, comprising expressing the polynucleotide of claim 72 in an isolated host cell.

Claim 90 (previously presented): An isolated polynucleotide comprising a sequence encoding a polypeptide, wherein the polypeptide comprises an immunoglobulin variable region containing the three light chain complementarity determining regions (CDRs) of antibody 11D10 or an immunoglobulin variable region containing the three heavy chain CDRs of antibody 11D10, wherein antibody 11D10 is produced by the hybridoma deposited under ATCC Accession No. HB-12020.

Claim 91 (previously presented): A polynucleotide according to claim 90, wherein the polypeptide comprises an immunoglobulin variable region containing the three light chain CDRs of antibody 11D10.

Claim 92 (previously presented): A polynucleotide according to claim 90, wherein the polypeptide comprises an immunoglobulin variable region containing the three heavy chain CDRs of antibody 11D10.

Claim 93 (previously presented): A polynucleotide according to claim 90, wherein the immunoglobulin light chain variable region is contained in SEQ ID NO:2.

Claim 94 (previously presented): A polynucleotide according to claim 90, wherein the immunoglobulin heavy chain variable region is contained in SEQ ID NO:4.

Claim 95 (currently amended): ~~The polynucleotide of claim 90~~ An isolated polynucleotide comprising a sequence encoding a polypeptide, wherein the polypeptide comprises an immunoblobulin variable region containing the three light chain CDRs of antibody 11D10 and the an immunoglobulin variable region containing the three heavy chain CDRs of antibody 11D10, wherein antibody 11D10 is produced by the hybridoma deposited under ATCC

Accession No. HB-12020, wherein the polypeptide has the light and heavy chain variable region sequences contained in SEQ ID NO:2 and SEQ ID NO:4, respectively.

Claim 96 (previously presented): A polynucleotide according to claim 90, wherein the encoding sequence is contained in the variable region encoding sequence in SEQ ID NO:1.

Claim 97 (previously presented): A polynucleotide according to claim 90, wherein the encoding sequence is contained in SEQ ID NO:3.

Claim 98 (previously presented): A composition comprising the polynucleotide of claim 90 and a pharmaceutically acceptable excipient.

Claim 99 (canceled)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
February 9, 2005

LARRY R. HELMS, PH.D
PRIMARY EXAMINER